



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,376	10/27/2003	Allen J. Brenneman	MSE #2650	5779

7590 08/03/2007
Jerome L. Jeffers, Esq.
Bayer Healthcare LLC
P. O. Box 40
Elkhart, IN 46515-0040

EXAMINER

TURK, NEIL N

ART UNIT	PAPER NUMBER
----------	--------------

1743

MAIL DATE	DELIVERY MODE
-----------	---------------

08/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/694,376

Applicant(s)

BRENNEMAN, ALLEN J.

Examiner

Neil Turk

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/27/03, 9/9/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Remarks

This Office Action fully acknowledges Applicant's remarks made on May 11th, 2007. Claims 1-14 and 21-24 are pending. Claims 15-20 have been cancelled. Claims 21-24 are newly added.

Election/Restrictions

Applicant's election without traverse of claims 1-14 and species I in the reply filed on May 11th, 2007 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis for the recitation, "...said lid adjacent said sample cavity..." Applicant has not previously recited that the lid is adjacent the sample cavity, but that the lid is approximately parallel to the light transmission path. Does Applicant intend to recite, "...wherein at least a portion of said lid is adjacent said sample cavity and is provided with a reagent thereon"?

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

Art Unit: 1743

regards as the invention. The recitation to, "adapted to be used" does not provide any positively recited structural elements that would function for such a use as currently recited. Currently the claim is directed toward an intended use without further limiting structure to the device. What additional structural elements are included in the format in order for such use with a measuring instrument and light guide of particular length?

Applicant must positively recite the additional structural elements to the format for such a use. Further, what is meant by the term "isolate" with respect to the length of the light input and the sample cavity? The term "sufficient length" is indefinitely defined as currently recited.

Claims 11, 12, and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The height of the light inputs and light transmission segment are undefined. The height must be structurally defined in relative terms so as to specifically establish which dimension is being called the height. As currently recited, the distance from end to end of the light inputs and light transmission segment could be defined as the height. This can be further seen in that the description of the light transmission segment is such that light travels across the segment between the two reflectors. This is likewise seen in defining the width of the venting cavity and main cavity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 7, 8, 11, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemelson (4,803,992).

Lemelson discloses a catheter or device 10 with an elongated housing 11 (lid with respect to claim 1) that includes a cable 21 that is formed of four separate light pipes 22 (input light guide), 24, 26, and 28 (output light guide). Lemelson further discloses that a cavity 16 is formed in the front end portion 13 that allows light energy to be directed therethrough to scan fluent material, such as body fluid existing in the cavity (line 38, col. 3 – line 2, col. 4; fig. 1). Lemelson also discloses that the device contains a plurality of reflecting surfaces 14 (input reflector) and 15 (output reflector) for respectively receiving light energy passed through the lens 23 of light pipe 22 from a source light and is then directed to reflect off reflecting surface 15 to receiving lens of the light pipe 28 along which it passes to a photoelectric detector coupled to the other end of light pipe 28 (lines 3-54, col. 4).

Art Unit: 1743

Claims 1-5, 7, 8, 10, 11, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Meserol (EP 0254246 A2).

Meserol discloses an improved cuvette. Meserol discloses a cuvette 10 in combination with a lancet 12, where the cuvette has a top 14 (lid) and a bottom 15, closed wall 18, access slot 20 (venting channel connected to the cavity), and a cavity 22 (for fluid, such as blood) (lines 25-40, col. 4, figs 1-4). Meserol discloses that the cavity 22 may be filled with a medium such as an optically transparent gel provided with a reagent test system (lines 8-21, col. 5). Meserol also discloses integrally formed optical elements, such as light beam 30 from source 32, which passes through the cuvette (input light guide is defined in the optically transmissive portion of the cuvette where light enters from source 32) and is reflected by reflecting prism 50 (input reflector) across cavity 22 to reflecting prism 48 (output reflector) and back out through the sample cuvette (output light guide is defined in the optically transmissive portion of the cuvette where light is reflected back and out of the cuvette) to optical element 36 (lines 1-42, col. 5; lines 10-41, col. 6, figs 5&6).

Art Unit: 1743

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol in view of Naka et al. (6,001,307), hereafter Naka.

Meserol has been discussed above.

Meserol does not disclose reagent provided on the lid.

Naka discloses an optical analyzing device in which when the covering 5a is transparent and light may be irradiated through the covering, a reagent film impregnated with a reagent may be stuck on the inner surface of the covering 5a (lines 38-46, col. 10, fig. 1a-b).

It would have been obvious to modify the Meserol device to include reagent provided on the lid such as taught by Naka, such that it would be obvious to place the

Art Unit: 1743

reagent on the lid (or any location), in which location the reagent will come into contact with the sample solution as desired.

Claims 12 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol.

Meserol has been discussed above.

Meserol does not disclose the specific dimension of the light guide, light transmission segment, main cavity, and venting cavity as recited in the above claims.

It would have been obvious through routine experimentation to optimize the Meserol device to the dimensions as recited in the claims in order to provide an optimal light path through the device.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol in view of Lundsgaard et al. (5,525,518), hereafter Lundsgaard.

Meserol has been discussed above.

Meserol discloses a lancet for obtaining a sample, but does not disclose that the lancet has a second end which deposits the sample into the cavity.

Lundsgaard discloses a needle 20 and sampling cavity connected for determination of a blood gas parameter in which the needle draws a blood sample through aperture 21 and into the conduit 21 down through measuring chambers 300, 400, 500, 600 (lines 52-67, col. 7, fig. 3).

Art Unit: 1743

It would have been obvious to modify the Meserol device such as taught by Lundsgaard to provide the other end of the lancet for deposition of the sample into the cavity in order to allow for direct sample deposition on to the test area, so as to avoid any loss of sample incurred from taking the pierced patient's skin and wiping sample into the cavity.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Turk whose telephone number is 571-272-8914. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HT

Jill Warden
Jill Warden
Supervisory Patent Examiner
Technology Center 1700